



**Testimony Before the Subcommittee on
Technology and Innovation
Committee on Science and Technology
U.S. House of Representatives**

**Statement for the Record for
hearing entitled, “Small Business
Innovation Research
Reauthorization on the 25th
Program Anniversary”**

Statement of

Norka Ruiz Bravo, Ph.D.

Deputy Director for Extramural Research

Office of Extramural Research

National Institutes of Health

U.S. Department of Health and Human Services

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Statement for the Record

Chairman Wu, Ranking Member Gingrey, and Members of the Subcommittee: I am Dr. Norka Ruiz Bravo, Deputy Director for Extramural Research at the National Institutes of Health (NIH), an agency of the Department of Health and Human Services (HHS). The NIH is the primary Federal agency for conducting and supporting biomedical research.

I appreciate the opportunity to provide for the record testimony about the Small Business Innovation Research (SBIR) program and the Small Business Technology Transfer Program (STTR) and ways to strengthen the participation of small businesses in the NIH SBIR/STTR programs.

IMPORTANCE OF SBIR/STTR PROGRAMS AT NIH

The NIH mission is to uncover new knowledge that will lead to better health for everyone. Helping to lead the way toward important medical discoveries, NIH-supported scientists investigate ways to prevent disease as well as investigate the causes, treatments, and cures for diseases and disabilities. The key to achieving our mission is that the rapid and fundamental advances in biomedical and behavioral sciences will be translated into prevention strategies and clinical treatments for rare and common diseases and then further applied to real-world practice. With new scientific discoveries comes the opportunity for small businesses to translate research results into the commercial marketplace.

The SBIR/STTR programs provide qualified small business concerns with opportunities to propose innovative ideas and to explore their technological potential. Projects funded

through the NIH SBIR/STTR programs focus on commercialization of the outcomes of research. The SBIR/STTR programs are fully integrated into the NIH research agenda, particularly with respect to promoting innovative, cutting-edge research ideas, as well as translating scientific findings and advances into tangible benefits for the American people. Thus, they serve to supplement – but not supplant or diminish – the traditional research programs of NIH.

The NIH SBIR program and STTR program represent about 98 percent and 100 percent, respectively, of HHS' programs in these areas. The NIH contributes the second largest amount of SBIR/STTR funding across the Federal government. In fiscal year (FY) 2006, the NIH SBIR program provided over \$580 million to fund 1,275 new Phase I (feasibility testing) and Phase II (product research and development) SBIR projects. We provided more than \$70 million to fund nearly 200 new Phase I and Phase II STTR projects. Since the programs' inception, the NIH has invested more than \$5 billion in more than 19,000 projects to over 5,000 small businesses.

PROGRAM EFFECTIVENESS: BRINGING IDEAS TO LIFE

The NIH SBIR/STTR programs are focused on creating research opportunities for U.S. small businesses to stimulate technological innovation and to translate discoveries into products/services that will improve human health. The programs seek to fund the most scientifically promising projects for which private and public funds are not traditionally available. As noted from the few examples below, the program has shown that tangible scientific benefits can result from a small investment in early-stage ideas with commercial potential but uncertain verification or feasibility.

- GlycoFi Inc. (NH), a biotherapeutics company, used the NIH SBIR program to explore the feasibility of making injectable proteins – so called “biotech drugs” – using a glycoengineered yeast strain. GlycoFi’s work is an example of exciting translational research where they use an innovative approach called *GlycoDesign*[™] to control a protein’s glycans (sugars) in order to optimize a therapeutic protein. GlycoFi demonstrated successfully the technical feasibility to develop a yeast system for producing therapeutic drugs in large scale. In May 2006, this six-year-old company was acquired by Merck & Co. for about \$400 million in cash, the largest such deal ever reported for a private biotechnology company.
- IntraLase Corporation (CA) used SBIR funding to develop a safer and more precise way to create the corneal flap in LASIK surgery. Today, using a bladeless technology to generate light pulses as short as one-quadrillionth of a second, IntraLase’s femtosecond laser technology is improving the safety and efficacy of laser vision correction.
- Electrical Geodesics Inc. (OR) has used the SBIR program to develop important research tools. It has developed a new generation of high-resolution electroencephalogram (EEG) measurement and analysis systems for use in medicine, psychology, and neuroscience research. Based on a patented Geodesic Sensor Net technology, EGI’s systems are now in use in research laboratories in the U.S., Europe, and Asia, in projects ranging from infant language comprehension to EEG pathology in dementia.

- Altea Therapeutics (GA) has used NIH SBIR funding to develop the PassPort™ System, which enables fast, controlled delivery of drugs (e.g., insulin) and vaccines painlessly through the skin using a needleless infusion patch.

These examples demonstrate why the SBIR/STTR programs are important to the innovation process. Marking the 25th year of the existence of the SBIR program, the time is ripe to reflect on how the programs have evolved and matured over time and to consider ways to develop program operations to improve program efficiency and effectiveness.

PROGRAM FLEXIBILITY IS KEY: ONE SIZE DOES NOT FIT ALL

The SBIR program now includes 11 participating agencies, each with very diverse missions. NIH attributes the success and effectiveness of its program to several factors, the most significant of which is flexibility in our proactive administration of the program to accommodate the changing nature of biomedical and behavioral research while increasing the efficiency and effectiveness of the program. These changes were focused on addressing the needs of a diverse business community, including multiple industries, different technology sectors, and diverse product outcomes.

Examples of program flexibility include the ability to provide funding levels that in some instances exceed the norm established in Small Business Administration (SBA) guidelines; the ability to propose research projects in the fields that have the most biological potential; the use of less rigid receipt dates; the permissibility of application resubmissions and gap funding options, including a Phase I/Phase II Fast-Track option to accelerate projects that have great potential for commercialization; and the

opportunity to compete for Phase II Competing Renewal awards for projects that must address FDA regulatory requirements (e.g., clinical evaluation).

Simply stated, one size does not fit all. Flexibility is key, particularly in addressing the current challenges noted below.

PHASE I/PHASE II AWARD LEVELS

The median award size in FY 2006 was \$143,725 for Phase I and \$415,952 per year for Phase II projects. Our experience is that the conduct of certain types of biomedical research, such as nanotechnology, clinically-related studies, vaccine development, and drug discovery, do not routinely lend themselves to prescribed maximum time and dollar levels. NIH appreciates the flexibility that the SBA has provided to exceed their guidelines, where appropriate, for particular projects, rather than to restrict ideas to projects that can only be conducted under a prescribed amount of time and money. Accordingly, we encourage small business concerns to propose realistic budgets and project periods appropriate for the successful completion of an SBIR project.

SMALL BUSINESS PARTICIPATION

Outreach is an important link to the participation of small businesses in the SBIR/STTR programs. We are continually enhancing our outreach efforts at conferences and forums aimed at increasing participation of all small businesses, and particularly socially and economically-disadvantaged and women-owned small businesses; the *Small Business Veterans Conference* and the *Alabama A&M University 2007 SBIR/STTR Small Business Conference* are just two examples. In addition to outreach, NIH provides administrative supplements to NIH SBIR/STTR awardees to improve the diversity of the

research workforce by supporting and recruiting students, postdoctorates, and eligible investigators from groups that have been shown to be underrepresented.

SUSTAINING THE INTEGRITY OF THE SBIR PROGRAM

Small businesses are increasingly recognized as important contributors and partners to technological innovation. Yet small business participation in the NIH SBIR/STTR programs is experiencing another trend of decreases. SBIR/STTR has been decreasing since FY 2004, as it did in FY 2001, at a time when non-SBIR applications have increased significantly. In FY 2006, NIH saw a nearly 15 percent decrease from the number of SBIR applications submitted in FY 2005 (see chart below). This reoccurrence of decreases is of serious concern to NIH, and we understand that several other agencies are also experiencing a decrease in submissions.

Percentage Change in Applications from Prior Fiscal Year:	
<u>Fiscal Year</u>	<u>Ph I and Ph II Application Base</u>
2000	11.0%
2001	-13.0%
2002	12.8%
2003	25.4%
2004	19.0%
2005	-11.9%
2006	-14.9%

The downward trend may be the result of several factors. Some firms are no longer eligible. Some have gone out of business. Some firms are new start-ups that have not yet fully developed the necessary infrastructure to successfully compete for an award. Some believe the time and cost for applying relative to the award levels is not a sufficient opportunity incentive. (Only about one-third of our SBIR and STTR awardees

are new to the program each year.) NIH encourages small businesses to participate in the SBIR/STTR programs and to use the programs as one, but not the only, resource for funding innovative, commercially viable ideas. In considering ways to increase the participation of innovative small businesses in the SBIR/STTR programs, NIH plans to give preference to new firms that have never received NIH SBIR/STTR awards and/or to firms that respond to agency-specific priorities, given a firm's level of expertise and evidence of likely ability to produce innovative products.

FINANCING AND COMMERCIALIZATION ASSISTANCE PROGRAMS

SBIR/STTR program reauthorizations have consistently emphasized the goal of addressing financing gaps toward product commercialization by requiring agencies to include as a review criterion the commercial potential of proposed projects. To help NIH SBIR awardees navigate this proverbial "valley of death" and move their products into the marketplace, NIH has developed a menu of technical assistance programs that provide technical and/or commercialization assistance specific to the companies' individual needs. These programs are:

Technology Niche Assessment (TNA™) Program: The TNA™ program assesses the market opportunities and needs and concerns of the end-users and helps to discover new markets for possible entry.

CAP: CAP provides Phase II awardees with assistance in developing and implementing an appropriate business strategy that will help commercialize the products that have resulted from their SBIR research projects. CAP is having positive impacts on some SBIR companies seeking investments and partnerships. For example, Cytograft Tissue

Engineering (CTE) received SBIR funding that enabled the company to explore the potential of an innovative technology to create a living blood vessel called Lifeline™. This exciting medical advancement has potential for coronary bypass candidates, lower limb amputation candidates, and hemodialysis patients. As a CAP participant, CTE has raised \$17 million in private equity financing to fund some of their clinical studies.

Pilot Manufacturing Assistance Program: In FY 2007, NIH initiated a pilot assistance program together with the National Institute of Standards and Technology Manufacturing Extension Partnership (MEP) program to help companies with making manufacturing decisions when developing their operational transition strategies (e.g., method of scale up, quality control, prototyping, facility design, vendor identification and selection, plant layout).

NIH believes the technical assistance to SBIR awardees is very important in helping companies transition to the marketplace.

PARTNERS: GOVERNMENT AND SMALL BUSINESS

The overarching intent of the SBIR program was stated best by President Reagan in signing the initial legislation: “We in government must work in partnership with small businesses to ensure that technologies and processes are readily transferred to commercial applications.” As researchers tackle ever more complex biomedical challenges and the rising cost of scientific research, strategic partnerships between NIH and private industry are becoming more important for advancing science and communicating results of medical advances to improve the quality of life for all people.

NIH is committed to increasing the participation of small businesses in the SBIR/STTR programs, ensuring that only *small* business concerns receive SBIR/STTR awards, and encouraging the participation of new start-up SBIR/STTR firms by giving them preference in award selection, much like new investigators are often given preference in traditional research grant programs (see http://grants.nih.gov/grants/new_investigators/institute_center_practices.htm). We need to find ways to innovate and collaborate, and promote scientific advances, and take advantage of every opportunity to improve public health.

CONCLUSION

In conclusion, it is our intention and hope that SBIR/STTR programs will continue to maintain their integrity and ensure that technology developments will be translated and disseminated for the benefit of all Americans.

Thank you for the opportunity to share with you my thoughts regarding the SBIR/STTR programs.